DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 2, 3, 5, 10, 12, 16, 20, 25, 50, 54, 56, 58, 60, 70, 71, 200, 201, 202, 206, 207, 210, 211, 299, 300, 310, 312, 314, 316, 320, 333, 369, 510, 514, 520, 522, 524, 529, 800, 801, 807, 809, 812, and 860

[Docket No. 98N–0720]

Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of January 5, 1999 (64 FR 396), a direct final rule. The direct final rule amended FDA's regulations by removing references to the repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs. The direct final rule also removed references to the repealed antibiotic monograph regulations and to those regulations dealing with antibiotic applications. This document confirms the effective date of the direct final rule.

EFFECTIVE DATE: The effective date of the direct final rule published at 64 FR 396 is confirmed as May 20, 1999.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: FDA solicited comments concerning the direct final rule for a 75-day period ending March 22, 1999. FDA stated that the effective date of the direct final rule would be on May 20, 1999, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Therefore, under the act, the FDA Modernization Act, and authority delegated to the Commissioner of Food and Drugs, notice is given that no objections were filed in response to the January 5, 1999, final rule. Accordingly, the amendments issued thereby are effective May 20, 1999.

Dated: May 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12230 Filed 5–14–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98N–0040]

RIN 0910–AB52

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations on the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. FDA is issuing these regulations in accordance with the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). These regulations are intended to clarify existing regulations applicable to the approval of radiopharmaceutical drugs and biologics under the Federal Food, Drug, and Cosmetic Act (the act) and the Public Health Service Act (the PHS Act).

EFFECTIVE DATE: Effective July 16, 1999.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510; or George Q. Mills, Center for Biologics Evaluation and Research (HFM–573), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5097.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 22, 1998 (63 FR 28301), FDA published a proposed rule to implement section 122 of the Modernization Act (Pub. L. 105–115). Section 122(a)(1) of the Modernization Act directs FDA to issue proposed and final regulations on the approval of radiopharmaceuticals intended for use in diagnosing or monitoring a disease or a manifestation of disease in humans. The proposed regulations apply to the approval of in vivo radiopharmaceuticals (both drugs and biologics) used for diagnosis and monitoring.

The preamble to the proposed rule noted that FDA was in the process of revising and supplementing its guidance to industry on product approval and other matters related to the regulation of diagnostic radiopharmaceutical drugs and biologics, and stated that such guidance would address the application of the proposed rule. In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA announced the availability of a draft guidance for industry entitled ''Developing Medical Imaging Drugs and Biologics'' (medical imaging draft guidance). The guidance, when completed, will assist developers of drug and biological products used for medical imaging, including radiopharmaceuticals used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The guidance will also provide information on how the agency will interpret and apply provisions in the final rule on diagnostic radiopharmaceuticals.

In the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened until February 12, 1999, the comment period on the medical imaging draft guidance. In the **Federal Register** of February 16, 1999 (64 FR 7561), the agency further extended the comment period to April 14, 1999.

Several of the comments on the proposed rule on diagnostic radiopharmaceuticals addressed issues that are also relevant to the medical imaging draft guidance. In FDA's responses to the comments set forth in section III of this document, the agency refers to relevant portions of the draft guidance that interpret and apply provisions of the regulations on diagnostic radiopharmaceuticals. In finalizing the medical imaging guidance, FDA will carefully consider all comments received on the proposed rule that are relevant to issues addressed in the draft guidance.

II. Highlights of the Final Rule

In accordance with section 122 of the Modernization Act, the final rule adds new regulations pertaining to the review and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring. The new regulations in part 315 (21 CFR part 315) and part 601 (21 CFR part 601) (§§ 601.30 through 601.35)) complement and clarify existing regulations on the approval of drugs and biologics in part 314 (21 CFR part 314) and part 601, respectively. The regulations include a definition of diagnostic radiopharmaceuticals and